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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,001	01/25/2002	Christopher A. Helliwell	021565-108	7679
21839	7590	05/19/2004	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			NGUYEN, QUANG	
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1636

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

347.

Office Action Summary**Application No.**

10/055,001

Applicant(s)

HELLIWELL ET AL.

Examiner

Quang Nguyen, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2003 and 04 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 18, 19, 23 and 28-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 23 and 28-33 is/are rejected.
- 7) ☒ Claim(s) 13-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/2/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amended claims 1-33 are pending in the present application.

Applicant's election with traverse of Group II (claims 1-12 and 20-21) in the amendment filed on 8/29/03 is acknowledged. The traversal is on the following ground(s):

1. The vectors claimed in Groups I, II and VIII are all acceptor vectors which allow the generation of chimeric genes which can be transcribed into dsRNA or RNAi, suitable for gene silencing of a target nucleic acid of interest. Applicants further argue that it is the presence and arrangement of these recombination sites which is essential to the utility of the claimed vectors - - specifically, as an acceptor vector in recombinational cloning to generate chimeric genes with an inverted repeat in the transcribed region - -, and the particular promoter used to transcribe the chimeric gene is manifestly not essential to the utility of the claimed vectors.

Upon reconsideration, Examiner decides to rejoin the vectors claimed in Groups I and II, drawn to an acceptor vector containing a promoter or promoter region capable of being recognized by RNA polymerases of a eukaryotic cell. With respect to the vector of Group VIII, Applicants' argument is not found persuasive because a promoter or promoter region capable of being recognized by a prokaryotic RNA polymerase is distinct and has no substantial common core structure of a promoter or promoter region capable of being recognized by a eukaryotic RNA polymerase present in the vectors of Groups I and II. Furthermore, the promoter is essential for the generation of chimeric genes which can be transcribed into dsRNA or RNAi, suitable for gene silencing of a

target nucleic acid of interest in a prokaryote or a eukaryote, depending on the presence of an appropriate promoter.

2. The vectors claimed in Groups III, IV, V, VI and VII are particular acceptor vectors characterized by their specific nucleotide sequences, and that they also share substantial structural features disclosed as being essential to generate chimeric genes with an inverted repeat in the transcribed region with the presence of the four recombination sites, in the order and as characterized by claims 1 and 18. These specific vectors also all comprise a CaMV35S promoter, which is a plant expressible promoter.

In light of Applicants' amendment, Examiner decides to rejoin the vectors claimed in Groups III, IV and VII together with the vectors claimed in Groups I and II. Please note that all of these vectors contain a promoter or promoter region capable of being recognized by RNA polymerases of a eukaryotic cell. Therefore, Applicant's arguments are moot.

3. With respect to the inventions of Groups IX and X, Applicants argue that claims directed towards a compound (i.e. the acceptor vectors of Group I, II or VIII) and a method of making that compound are allowable in one application.

It should be noted that the inventions of Groups IX and X are drawn to methods of using the acceptor vectors of Group I, II or VIII, and not methods of making the acceptor vectors. Upon reconsideration, Examiner decides to rejoin the invention of Group IX, drawn to a method for making a chimeric DNA construct capable of expressing a dsRNA in a eukaryotic cell *in vitro*, using the acceptor vectors of Groups I-

VII. The inventions of Groups IX and X are distinct *in vitro* and *in vivo* methods for making a chimeric DNA construct, respectively, for the reasons already set forth in the previous Office Action mailed on 7/29/03.

4. Applicants argue that the MPEP indicates that claims directed towards a compound (i.e., the acceptor vectors of Group I, II or VII), and a method of using that compound are appropriate in one application. Therefore, at least Groups XI and XII should be rejoined with the elected invention.

This is not found persuasive because the methods of Groups XI-XIV are not methods of using the acceptor vectors of Groups I-VII, but rather methods of using products generated from another method of using the acceptor vectors of Groups I-VIII. Examiner further notes that Applicants did not distinctly and specifically point out why the inventions of Groups XI-XIV are not distinct.

Upon further consideration, the species restriction is also withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Claims 18-19, 23, 28-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the amendment filed on 8/29/03.

Accordingly, claims 1-17, 20-22 and 24-27 (Groups I-VII and IX) are examined on the merits herein.

Priority

On page 1, paragraph [002], Applicants are requested to amend the continuing data to indicate that the instant application claims priority to U.S. Provisional Application Serial No. 60/264,067, filed January 25, 2001, and U.S. Provisional Application Serial No. 60/333,743, filed November 29, 2001, rather than a continuation-in-part to the aforementioned U.S. Provisional Applications.

Upon review of the specifications of the provisional applications 60/264,067 and 60/333,743 and comparison with the specification of the present application, it is determined that claims 14-17 are only entitled to the priority benefit of the filing date of 11/29/2001. This is because SEQ ID NOs. 23-26 are first mentioned in the provisional application 60/333,743.

Accordingly, claims 14-17 are only entitled to the priority benefit of the filing date of 11/29/2001; whereas claims 1-13, 20-22 and 24-27 are entitled to the priority benefit of the filing date of 1/26/2001.

Specification

The abstract of the disclosure is objected to because of the legal phraseology "means" online 1 of the abstract. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 38, line 2). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Objections

Claim 6 is objected to because it is apparently that the term - - and - - in line 5 of the claim is inadvertently misspelled. Appropriate correction is required.

Claim 26 is objected to because the terms "IHF", "Int", "Xis" and "IHF" should be spelled out in full at the first occurrence of these terms. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 20-22 and 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent

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protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "allowing replication in a recipient cell", and the claim also recites "preferably in bacteria" and "particularly in *Escherichia Coli*." which are the narrower statements of the range/limitation. Additionally, claim 1 recites the broad recitation "a same recombination site", and the claim also recites "preferably are identical" which is the narrower statement of the range/limitation.

Claim 6 recites the limitation "said selectable marker genes" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim. In claim 1 which claim 6 is dependent, only a selectable marker region is recited. Therefore, the metes and bounds of the claim are not clearly determined.

Claim 22 recites the limitation "said product DNA molecule" in line 14 of the claim. There is insufficient antecedent basis for this limitation in the claim. Prior to this limitation, claim 22 recites "product DNA molecules". Therefore, which said DNA

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molecule does Applicants refer to? The metes and bounds of the claim are not clearly determined.

Conclusion

No claims are allowed.

Claims 13-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (703) 872-9306.

Quang Nguyen, Ph.D.


DAVID GUZO
PRIMARY EXAMINER